



Design of an ecological momentary assessment study of exposure to radiofrequency electromagnetic fields and non-specific physical symptoms

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3 **Design of an ecological momentary assessment study of exposure to radiofrequency**
4 **electromagnetic fields and non-specific physical symptoms**
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ABSTRACT

Introduction. Idiopathic Environmental Intolerance (IEI) attributed to electromagnetic fields (EMF) refers to self-reported sensitivity mainly characterized by the attribution of non-specific physical symptoms to low-level electromagnetic field (EMF) exposure emitted from sources such as mobile phones. Scientific studies have not provided evidence for the existence of electro hypersensitivity, but these studies did not resemble the real-life situation or suffered from poor exposure characterisation and biased recall of health symptoms. To improve existing methods for the study of electro hypersensitivity, an Ecological Momentary Assessment (EMA) study is designed.

Methods and analysis. The study is an EMA study in which respondents carry personal exposure meters (exposimeters) that measure RF EMF, with frequent assessment of health complaints and perceived EMF exposure through electronic diary registration during five consecutive days. Participants will be a selection of participants from an epidemiological study who report to be sensitive to RF EMF. The exposimeters measure electric field strength in 12 frequency bands. Diary questions include the occurrence and severity of 10 non-specific physical symptoms, mood states, and perceived exposure to (sources of) EMF. The relationship of actual and perceived EMF exposure and mood with non-specific physical symptoms will be analysed using multilevel regression analysis with time-shift models.

Discussion. The panel study has several advantages over previous studies, including assessment of personal EMF exposure and non-specific physical symptoms by an ecological method with a minimised chance of recall bias. The within-person design reduces confounding by time-stable factors (e.g., personal characteristics). In the conduct of the study and the analysis and interpretation of its outcomes, some methodological issues including a high participant burden, reactivity, compliance to the study protocol, and the potential of chance findings due to multiple statistical testing will be accounted for and limited as much as possible.

ARTICLE SUMMARY

Article focus

- The article describes the design of an Ecological Momentary Assessment (EMA) study to determine if non-specific physical symptoms in persons who self-report to be sensitive to radiofrequency electromagnetic fields (RF EMF) can be explained by objectively measured exposure to RF EMF, or by psychological measures such as perceived exposure and mood.

Key messages

- The EMA design of the study combines true personal RF EMF exposure measurements with momentary measured health symptoms, perceived RF EMF exposure and mood.

Strengths and limitations of this study

- Both personal EMF exposure and non-specific physical symptoms will be assessed by ecological methods with a minimised chance of recall bias.
- Issues to be aware of include a high participant burden, reactivity, compliance to the study protocol, and the potential of chance findings due to multiple statistical testing.

INTRODUCTION

Some people experience subjective health symptoms in the proximity of (specific sources or frequencies of) radiofrequency electromagnetic fields (RF EMF). Sources of RF EMF in the home environment include mobile or DECT phones and their base stations, WiFi, microwave ovens, television and radio transmitters. Although there is lack of a validated case definition, when an individual attributes his/her health symptoms to EMF exposure, this is mostly referred to as electromagnetic hypersensitivity (EHS). Because of similarities with other (unproven) environmental intolerances, such as multiple chemical sensitivities, the World Health Organisation introduced the broader term Idiopathic Environmental Intolerance (IEI).[1] When afflicted persons attribute their illness to EMF, it is referred to as IEI-EMF. The health symptoms of electro hypersensitivity are non-specific and differ from person to person.[1] Frequently mentioned symptoms include fatigue, headaches, concentration problems, nervousness and tinnitus.[2] IEI-EMF has been found to be associated with limitations in social and occupational functioning.[3 4] The prevalence of IEI-EMF is estimated to be 1.5-5% of the population,[3 5 6] but also a prevalence as high as 13% has been reported.[7] These differences are due to the population under study (Western countries vs. Taiwan), and probably also the instruments or definitions that were used.[8] For the Netherlands, an estimate of the prevalence of electro hypersensitivity is not yet available.

Scientific studies have not provided convincing evidence for the existence of a causal bioelectromagnetic mechanism for non-specific health symptoms.[9] Alternative explanations for IEI highlight the role of psychological mechanisms such as hyper vigilance to threat stimuli, attention bias and somatosensory amplification.[10] For electro hypersensitivity, some findings suggest that *nocebo* responses account for the symptoms,[9 11] in which concerns about a perceived harm precede the development of symptoms. Indeed, electro hypersensitive persons have relatively high levels of mental distress, anxiety, depression, and worries about

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3 modern life.[12-14] Several studies have demonstrated a relationship between negative affect
4 and non-specific health complaints.[15]
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9 Most evidence for the lack of an association between EMF exposure and non-specific
10 physical symptoms is derived from short-term provocation studies in the laboratory, which
11 have been criticized because of their lack of internal and external (ecological) validity.
12 Criticisms include that at first, a visit to the laboratory may cause anxiety that influences the
13 results, that EMF exposure in the experimental setting does not resemble real-life EMF
14 exposure, and that follow-up times are insufficiently long to capture participants' responses
15 [9]. Observational studies are subject to other forms of bias due to errors in the recall of
16 symptoms (recall bias) and in the assessment of EMF exposure.[16]
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27 The limitations mentioned above can be solved by EMA. With EMA, the assessment is
28 momentary, on the spot in real-life, and captures life as it is lived.[17 18] More precise and
29 ecologically valid EMA-measurement of personal RF EMF exposure can be performed with
30 exposimeters[19] This produces more valid estimates than other methods such as self-
31 reported exposure, geo-coded distance from sources of RF EMF (e.g. base stations) or spot
32 measurements.[20] Recall bias of symptoms can be minimised by using EMA diary methods
33 with short time frames instead of asking participants to retrospectively report (the usual
34 frequency of) symptoms over a prolonged period.[21]
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46 This article describes the design of an EMA study on the relationship between real-life
47 measured and perceived exposure to RF EMF and the real-time experience of non-specific
48 physical symptoms and mood in self-declared electro hypersensitive people. The study
49 intends to minimise sources of bias by using exposimeters to estimate RF EMF exposure and
50 real time on the spot assessment of symptoms.
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Objectives

The key objective of the study is to determine if in a period of a few days non-specific physical symptoms in persons who report to be sensitive to RF EMF can be explained by objectively measured exposure to RF EMF, or by psychological measures such as perceived exposure and mood. Secondary objectives are to study the manifestation of non-specific symptoms in terms of severity and duration of symptoms, the lag time – in hours to days – between exposure and the presentation of symptoms, and to characterise RF EMF exposure of electro hypersensitive persons.

METHODS AND ANALYSIS

Study design

Epidemiologic panel studies have been described as ‘prospective studies that follow a usually small group of individuals intensively over a short time period [...] with the objective to study short-term effects of a time-varying environmental exposure’.[22] A main advantage of a panel design is the availability of measurements of exposure and health outcomes at an individual level. The present study is an EMA study in which, for five consecutive days, participants carry a measurement set consisting of an RF EMF personal exposure meter, a so called exposimeter, a GPS (global positioning system) logger and an electronic diary. The electronic diary assesses health complaints, perceived exposure and mood. It has to be completed directly at frequent, random alarm cues, as this prevents both recall bias and possibly planned high exposures shortly before the time when filling out the diary. This design allows for studying whether non-specific physical symptoms are preceded by exposure to EMF, using various latency times, and/or whether these symptoms are related to psychological variables such as perceived exposure and mood.

Selection of study population

Participants will be recruited from an existing epidemiological study (EMPHASIS) on non-specific physical symptoms and their relation with model-estimated actual and perceived EMF exposure.[23] This study includes 6304 persons that were selected from 21 general practices throughout the Netherlands, varying in level of urbanisation and stratified according to the distance of their residencies to a mobile telephone base station. The response rate to the written questionnaire was approximately 50%.[24]

Participants will be selected from the respondents to this survey based on self-reported sensitivity to EMF measured with a five-point scale. People who indicated to fully or partly agree with the statement 'I am sensitive to antennas and devices using wireless communication (e.g., for radio, television, mobile phones, wireless internet etc.)' and who gave their consent to use their address for re-approaching, will be invited by post to participate in the panel study. All study materials (diaries, exposimeters, and instructions) will be delivered at the participants' homes, where they will be orally instructed about the study procedures.

Electronic diaries

Diary methods are considered to be suitable to examine self-reported events and experiences in their natural, spontaneous context. Benefits of diary methods are that bias in the recall of events and experiences is reduced because the time between the occurrence of an event or experience and its reporting is minimised.[17]

Research questions that can be properly addressed using diary methods, and that constitute the main questions of the present study include: what are the processes (antecedents, correlates) that cause within-person variability in daily experiences, and how do people differ in these processes.[17]

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3 The present study will use electronic diaries. Advantages of electronic diaries include a higher
4 participant compliance than paper and pencil diaries,[25] control of alarm cues, and a detailed
5 log file for compliance check.
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10 For diary keeping we will use *LG P-500 Optimus One* smartphones running on Android 2.3.
11 Because the study population will consist of electro hypersensitive people, the phone operates
12 in flight mode without a SIM card. A check of exposure to extremely low frequencies (Emdex
13 Lite, Enertech Consultants, California) and RF (EME Spy 121, Satimo, France) confirmed
14 that the exposure from the smartphone was negligible, i.e. below the detection limits.
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20 Special software for the diaries was developed using Java (Android version 2.2 or higher).
21 The diary programme is based on software written for Palm-OS personal digital assistants
22 which has been developed and used by Houtveen et al..[26] A sampling protocol with a mean
23 interval of 2.5 hours and random variation of ± 30 minutes will be used that continues from
24 awakening till bedtime. This sampling scheme leads to approximately 8 alarms per day (based
25 on a 16-h awakening period). Diary prompting will only be disabled during sleep, initiated by
26 a button on the smartphone. The smartphone can be used as a morning alarm, and prompting
27 continues after awakening. All unused buttons are blocked. Alarms without response are
28 repeated (max 3 times with 10-min time intervals). The alarm software generates a log-file
29 containing alarm and response times to be used for determination of the compliance. The
30 questionnaire can be launched by a start button that is visible for 5 min after prompting. All
31 questions are forced-choice, and are displayed as sequential screens on the smartphone.
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48 Participants will not be allowed to leaf through the present or previous diaries. The volume of
49 the alarms is adjustable and there is the possibility to temporarily mute the alarm.
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Diary questionnaire

The diary questionnaire consists of 32 items. In the morning and evening, 5 and 8 additional questions are included, respectively. According to guidelines for diary questions, the items are short, simply worded, and try to mimic the participants' internal dialogue, e.g. 'at the moment, I suffer from headache'.

General health status and non-specific physical symptoms

General health status will be assessed by using the first question from the RAND-36.[27] Nine symptoms are selected that are most often reported by electro hypersensitive people according to studies in Switzerland[2] and a study by the Dutch Electrohypersensitivity Foundation.[28] These symptoms comprise of fatigue, distressed/nervous/tense feeling, concentration problems, tinnitus, dizziness or light-headedness, painful joints or muscles, skin problems, problems with vision, hearing or smell. In addition, one question asks for the symptom that the participant usually experiences and that is not in the pre-specified list. For all symptoms the momentary experience is assessed ('at this moment, ...'). Response options range from 'not at all' to 'very much' on a five-point Likert response format with only the extremes labelled.

Perceived exposure to (sources of) RF EMF, noise and air pollution

Perceived exposure to RF EMF will be assessed both momentary and for the interval between alarm cues, using the question 'At the moment/since the last alarm cue, I am exposed to radio frequent electromagnetic fields', with response options ranging from 'not at all' to 'very much' on a five-point scale with only the extremes labelled. Perceived exposure to specific sources of RF EMF is assessed by asking the participant to indicate which of the following sources mainly determined their exposure: mobile phone, DECT phone, WiFi, antennas for mobile telephony, radio or television masts, another source.

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3 Momentary (but not for the interval between alarm cues) exposure to noise and air pollution
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5 are asked in a similar way.
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8 9 Environment

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11 In order to interpret the readings of the exposimeter, participants will be asked to indicate in
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13 what kind of environment they were during the interval between alarm cues. The
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15 environments included are at home inside, at home outside, elsewhere inside, elsewhere
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17 outside, on the road (on foot, by bike, car or public transport), in the city centre or a shopping
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19 area, in a residential or built-up area but not the centre, outside the built-up area (e.g., in a
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21 rural area or in nature). All participants already completed a detailed time-activity
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23 questionnaire on their general behaviour in the EMPHASIS study.
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26 27 Self-reported use of mobile phone and DECT phone

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29 Phone use will be estimated separately for mobile phones and DECT phones by asking how
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31 many minutes a person called in the interval between alarm cues: 1-5, 5-10, 10-10, 20-30, 30-
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33 60 or longer than 60 minutes.
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36 37 Mood

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39 The Profile of Mood States (POMS)[29] will be used to assess momentary (state) depression,
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41 vitality, anger, and tension. Three items for each subscale will be used, as was done
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43 previously by Houtveen and Van Doornen.[30] The selected items were: (1) depression:
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45 unhappy, sad, hopeless, (2) vitality: active, energetic, lively, (3) anger: angry, annoyed,
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47 moody, (4) tension: tense, nervous, anxious. Each item can be rated using a five-point Likert
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49 response format ranging from 'not at all' to 'very much' with only the extremes labelled.
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52 53 Additional questions

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3 After the morning alarm cue, the diary contains some questions about the duration and quality
4 of sleep. Before the participants go to bed, questions are asked about use of medication to
5 relieve their symptoms (mentioned in the diary), and whether the participants rested or took a
6 nap during daytime.
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10 11 **Personal RF exposure assessment**

12 Actual EMF exposure will be measured using EME-SPY 121 exposimeters (Satimo,
13 Cortaboeuf, France) worn at the hip in a camera bag. As the maximum memory capacity of
14 the exposimeter is 12,540 sampling intervals and the study will last for 120 hours, the
15 exposimeter will measure at an interval of 36 seconds. The exposimeters measure the RF
16 electric field strength in 12 frequency bands used for communication and broadcasting (see
17 Appendix 1). Before the exposimeters will be employed in the study, they will be calibrated
18 according to a previously described method.[19]
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28 The participants will be instructed to wear the exposimeters all day except during wet
29 activities (e.g. showering) and sports (to avoid damage due to shocks). During sleep the
30 exposimeters have to be placed next to the bed within 50 cm from the head. The electronic
31 diary contains an event button that can be used to indicate when the exposimeters are worn or
32 taken off.
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40 **GPS logger**

41 Participants will wear a GPS device at their left shoulder. The GPS logger geo-locates the
42 personal RF EMF measurements and the data can be used to visualize the participants'
43 location and measured EMF exposure on a Google Earth map.[31 32] This visualization can
44 be used to interpret and check the quality of the EMF measurements.
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51 **Data analysis**

52 Exposimeter data will be aggregated either over fixed time intervals or over intervals between
53 random alarm cues, and for each interval the time weighted average, peak exposure, exposure
54 above a certain threshold and rate of change can be calculated for all frequency bands
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3 separately and combined. The relationship of actual and perceived EMF exposure with non-
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5 specific physical symptoms will be analysed using multilevel regression analysis. The within-
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7 subject repeated measurements of actual and perceived EMF exposure and mood will be the
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9 first-level variables, which will be modelled as fixed effects; the second level will be the
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11 individuals and will be modelled as random effects. Because time (hour of the day) is
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13 associated with symptom occurrence and severity (e.g. for fatigue), this will be included in
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15 the model using a sinus-cosinus 24 hour function to account for the diurnal pattern. Unique
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17 contributions of the various explanatory variables will be estimated in multivariate models, in
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19 which an intercept, 24 hour time function, actual EMF exposure, perceived EMF exposure
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21 and mood will be included. Time-shift models with different lag times will be used to gain
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23 insight in the time delay between exposure and mood and the occurrence of symptoms. The
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25 time window of five days should be sufficient to capture the potential participants' response
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27 to EMF exposure, based on reported latencies between exposure and symptoms.[2]

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29 A multilevel power analysis was performed to calculate the strength of the association
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31 between perceived EMF exposure and nonspecific physical symptoms that could be detected
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33 with the repeated measurements multilevel analysis in a sample of 60 volunteers with each 40
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35 (5 days with 8 measurements) observations. Thereby using a significance level of 5% and a
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37 power of 80%. This method based on simulations is described in reference.[33] No such
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39 calculation was made for actual EMF exposure because most evidence points towards the
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41 absence of an association with nonspecific physical symptoms.

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43 Input parameters for the power analysis came from a pilot study of four (not electro
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45 hypersensitive) master students (two males, two females) who completed the diary questions
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47 for two weeks. Figure 1 illustrates how the power of the statistical analysis differs according
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49 to the magnitude of the regression coefficient. It can be seen that at a power of 80%, the
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51 detectable regression coefficient is slightly over 1.5.
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ETHICS AND DISSEMINATION

A formal written inquiry, including a detailed description of the study protocol, was made at the medical ethics committee of the University Medical Centre Utrecht to check if the study protocol should be tested within the framework of the Dutch Medical Research Involving Human Subjects Act. A formal advice was received in which the Committee indicated that the study was exempt from having to pass the full ethics testing procedure. Handling of personal data will comply with the Personal Data Protection Act [in Dutch: Wet bescherming persoonsgegevens (Wbp)]. After removal of identifying information, data will be stored on a part of the institute's server with limited access by specified employees.

Results of the study will be offered for publication in the international peer-reviewed literature and presented at (international) conferences. Further, results will be disseminated at a national level at meetings organized by The Netherlands Organisation for Health Research and Development (ZonMw). At these meetings representatives of electrosensitive patient groups will also be reached.

DISCUSSION

The EMA design of this study is innovative as it combines true exposure measurements with momentary measured health symptoms. The design aims to circumvent important limitations of previous studies into electro hypersensitivity, which can be summarised as biased recall of health outcomes, poor characterisation of individual exposure to EMF, and experimental exposure conditions that substantially differ from the real-life situation (i.e. low ecological validity). Another potential strength of the study is the simultaneous assessment of actual and perceived EMF exposure. In the multilevel regression analysis, independent contributions of these two types of exposure can be estimated, an approach similar to the EMPHASIS study.[23] With respect to recall bias, it has been shown that especially in people with high levels of non-specific physical symptoms, less symptoms are reported when using momentary assessment methods compared to retrospective methods.[34] Since electro hypersensitive

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3 persons typically report more symptoms than the general population,[35] a symptom diary is
4 more suitable to obtain a valid estimate than asking to report the usual or average number of
5 symptoms retrospectively.
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11 Regarding the EMA-measurement of exposure, exposimeters are the method of choice to
12 measure personal exposure compared to spot measurements, self-estimated exposure, and
13 exposure prediction models.[20] Nevertheless, also measurements of exposimeters have their
14 own limitations and not always free of bias. To obtain valid measurements, it is important that
15 the participants receive clear and standardised instructions about how to wear the meters. In
16 this way measurements by different participants will be harmonised and more
17 comparable.[19] Exposure from mobile phone use by the participants themselves will not be
18 measured properly by the exposimeter, because the exposimeters are designed to measure the
19 far EMF field, i.e. exposure from EMF sources further away. Therefore, mobile phone use
20 during each 2.5 hour interval between alarm cues is asked for in the diaries (although we are
21 aware of the recall bias in the estimates of self-reported phone use).
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35 Another strength of using individual-level exposure and outcome data is that confounding by
36 factors that remain stable over time is reduced, because within-subject variation in exposure
37 and manifestation of health symptoms are of primary interest. Thus, the analyses do not
38 require adjustment for personal characteristics such as demographic factors and psychological
39 traits. However, to detect possible interaction effects, e.g. different associations in men and
40 women, personal characteristics have to be taken into account. The multilevel regression
41 analysis allows for such an investigation of cross-level interactions. Because the study
42 population may be a mix of 'truly' electrosensitive individuals and individuals in whom
43 psychological mechanisms account for their symptoms, we will explore the applicability of
44 statistical methods to study associations that differ between individuals (vector autoregressive
45 models[36]).
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3 Time-varying factors associated with EMF exposure [32] that potentially affect symptom
4 occurrence also need to be accounted for. Avoidance of EMF exposure after symptoms start
5 to develop is such a factor. Time-varying factors associated with symptoms but not with EMF
6 exposure are no confounders, but can obscure relationships between exposure and symptoms.
7 This is the reason a question about the use of medication to relieve symptoms and rest/sleep
8 during the day is included in the diary questionnaire.
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17 There are also limitations to the described study. The study involves relatively high costs in
18 terms of the necessary equipment and work. The exposimeters are expensive and vulnerable
19 to physical damage, and the electronic diaries are also costly compared to traditional paper
20 and pencil diaries. Also, the programming of the diary software is very time consuming. As a
21 result, only a limited number of participants can be included in the study. The burden for
22 participants is quite high, since they have to carry the exposimeters and GPS loggers with
23 them and are interrupted by the diary alarm cues several times a day. It is expected that only
24 highly motivated persons will participate, but because the study is not intended to examine a
25 representative sample of the population this is not considered a problem. Compliance to the
26 study protocol may be difficult for some participants because they may find wearing the
27 exposimeter awkward. As a result of participation in the study, the participants' attention to
28 EMF exposure and physical symptoms may increase (reactivity). It can in principle not be
29 excluded that the data are manipulated by placing the meters next to a (assumed) source of
30 EMF before an alarm cue is expected. To minimise the chance of such anticipation effects,
31 the alarms are programmed at random intervals.
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50 In the statistical analysis, false-positive associations due to multiple testing may arise. For
51 EMF exposure, there is information about 12 frequency bands which can be analysed
52 separately and combined. Possible exposure metrics include time-weighted average, peak
53 exposure, rate of change and exposure above a certain threshold. Since no biological
54 mechanism is known that explains how EMF can affect health, in theory each combination of
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3 almost 50 combinations of frequency and exposure metrics can be relevant. If associations
4 with symptoms are found, it is necessary to replicate the results to exclude chance findings.
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9 An issue that deserves attention is the selection of the study population. Since no objective
10 diagnostic tool for electro hypersensitivity exists, the only selection criterion for inclusion in
11 the panel study is self-reported sensitivity to RF EMF. No further selection will be made
12 based on the occurrence of non-specific physical symptoms as this is the outcome variable of
13 the study. Also, no exclusions will be made based on psychological variables. The reason for
14 this is that electro hypersensitivity often goes together with psychological problems such as
15 depression and anxiety,[12] and especially in the most sensitives psychiatric morbidity has
16 been reported to be high.[7] Therefore, by excluding persons based on psychological
17 characteristics the study population of interest may be missed. Somatic (chronic) diseases will
18 not be excluded either, as a considerable part of electrohypersensitive persons suffers from
19 chronic diseases,[35] and at this stage it is not possible to decide on theoretical grounds which
20 medical conditions should be included or excluded.
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35 A control group is not deemed necessary, since in the longitudinal study design each
36 participant acts as their own control. Moreover, if there are associations between RF EMF
37 exposure and symptoms, this will be most likely in persons who report to be sensitive to RF
38 EMF, and statistical power will be enhanced by focusing on this group. A limiting factor of
39 this approach is that we cannot verify if persons with IEI-EMF are more sensitive to EMF
40 than controls.
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50 In summary, this is the first time that actual and perceived exposure and possibly explanatory
51 variables are combined to such extent in an IEI-EMF sample. The main strengths of the study
52 described in this paper are an accurate assessment of EMF exposure and non-specific physical
53 symptoms using an EMA methodology, and elimination of confounding by personal
54 characteristics as a result of the within-person design. The methodological issues mentioned
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5 well as the analysis and interpretation of its outcomes.
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LIST OF ABBREVIATIONS USED

DECT: Digital enhanced cordless telecommunications

EMA: ecological momentary assessment

EMF: electromagnetic fields

RF: radiofrequency

COMPETING INTERESTS

The authors declare that they have no competing interests.

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AUTHORS' CONTRIBUTIONS

RPB conceived of the study, participated in its design and coordination, and drafted the manuscript. JFBB participated in the study design and helped to revise the manuscript critically for important intellectual content. JHH participated in the study design and helped to revise the manuscript critically for important intellectual content. EL conceived of the study, participated in the study design and helped to revise the manuscript critically for important intellectual content. RTvS participated in the study design and helped to revise the manuscript critically for important intellectual content. CMAS participated in the study design and helped to revise the manuscript critically for important intellectual content. MA programmed the electronic diary software and helped to revise the manuscript critically for important intellectual content. CB participated in the study design and helped to revise the manuscript critically for important intellectual content. IvK participated in the study design, permitted access to the EMPHASIS dataset and helped to revise the manuscript critically for important intellectual content. All authors read and approved the final manuscript.

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FIGURES

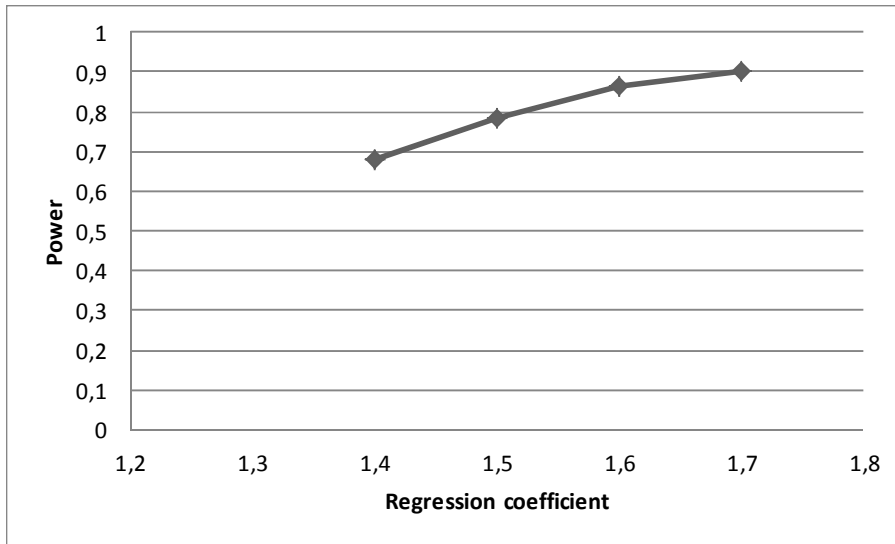


Figure 1. Power of the repeated measurements multilevel regression analysis as a function of the magnitude of the regression coefficient, $n=60$ persons with 40 repeated measurements.

APPENDIX 1

The 12 frequency bands measured by the exposimeter are: FM radio (88–108 MHz), TV3 (174–223 MHz), TETRA (380–400 MHz), TV4&5 (470–830 MHz), GSM uplink (880–915 MHz), GSM downlink (925–960 MHz), DCS uplink (1710–1785 MHz), DCS downlink (1805–1880 MHz), DECT (1880–1900 MHz), UMTS uplink (1920–1980 MHz), UMTS downlink (2110–2170 MHz), and WiFi (2400–2500 MHz). The formerly TV3 and TV4&5 frequency bands are nowadays used for digital radio, Terrestrial Digital Audio Broadcasting (T-DAB), and digital TV, Digital Video Broadcasting Terrestrial (DVB-T), respectively. Uplink means that the signal is used for the contact from mobile phone to base station, downlink is from base station to mobile phone.



Design of an ecological momentary assessment study of exposure to radiofrequency electromagnetic fields and non-specific physical symptoms

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Manuscripts

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9 4 KEYWORDS

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13 6 fields; personal exposure measurement; electronic diaries
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3 **ABSTRACT**

4 **Introduction.** Idiopathic Environmental Intolerance (IEI) attributed to electromagnetic fields
5 (EMF) refers to self-reported sensitivity mainly characterized by the attribution of non-
6 specific physical symptoms to low-level electromagnetic field (EMF) exposure emitted from
7 sources such as mobile phones. Scientific studies have not provided evidence for the existence
8 of IEI-EMF, but these studies did not resemble the real-life situation or suffered from poor
9 exposure characterisation and biased recall of health symptoms. To improve existing methods
10 for the study of IEI-EMF, an Ecological Momentary Assessment (EMA) study is designed.

11 **Methods and analysis.** The study is an EMA study in which respondents carry personal
12 exposure meters (exposimeters) that measure radiofrequency (RF) EMF, with frequent
13 assessment of health complaints and perceived EMF exposure through electronic diary
14 registration during five consecutive days. Participants will be a selection of participants from
15 an epidemiological study who report to be sensitive to RF EMF. The exposimeters measure
16 electric field strength in 12 frequency bands. Diary questions include the occurrence and
17 severity of 10 non-specific physical symptoms, mood states, and perceived exposure to
18 (sources of) EMF. The relationship of actual and perceived EMF exposure and mood with
19 non-specific physical symptoms will be analysed using multilevel regression analysis with
20 time-shift models.

21 **Discussion.** The study has several advantages over previous studies, including assessment of
22 personal EMF exposure and non-specific physical symptoms by an ecological method with a
23 minimised chance of recall bias. The within-person design reduces confounding by time-
24 stable factors (e.g., personal characteristics). In the conduct of the study and the analysis and
25 interpretation of its outcomes, some methodological issues including a high participant
26 burden, reactivity, compliance to the study protocol, and the potential of chance findings due
27 to multiple statistical testing will be accounted for and limited as much as possible.

1 ARTICLE SUMMARY

2 Article focus

- 3 • The article describes the design of an Ecological Momentary Assessment
4 (EMA) study to determine if non-specific physical symptoms in persons who
5 self-report to be sensitive to radiofrequency electromagnetic fields (RF EMF)
6 can be explained by objectively measured exposure to RF EMF, or by
7 psychological measures such as perceived exposure and mood.

9 Key messages

- 10 • The EMA design of the study combines actual personal RF EMF exposure
11 measurements with momentary measured health symptoms, perceived RF
12 EMF exposure and mood.

14 Strengths and limitations of this study

- 15 • Both personal EMF exposure and non-specific physical symptoms will be
16 assessed by ecological methods with a minimised chance of recall bias.
- 17 • Issues to be aware of include a high participant burden, reactivity, compliance
18 to the study protocol, and the potential of chance findings due to multiple
19 statistical testing.

1 INTRODUCTION

2 Some people experience subjective health symptoms in the proximity of (specific sources or
3 frequencies of) radiofrequency (RF) electromagnetic fields (EMF). Sources of RF EMF in the
4 home environment include mobile or DECT phones and their base stations, WiFi, microwave
5 ovens, television and radio transmitters. Although there is lack of a validated case definition,
6 when an individual attributes his/her health symptoms to EMF exposure, this is mostly
7 referred to as electromagnetic hypersensitivity (EHS). Because of similarities with other
8 (unproven) environmental intolerances, such as multiple chemical sensitivities, and because
9 scientific evidence of a causal relationship between EMF exposure and symptoms is lacking,
10 the World Health Organisation introduced the broader term Idiopathic Environmental
11 Intolerance (IEI).[1] When afflicted persons attribute their illness to EMF, it is referred to as
12 IEI-EMF. The health symptoms of IEI-EMF are non-specific and differ from person to
13 person.[1] Frequently mentioned symptoms include fatigue, headaches, concentration
14 problems, nervousness and tinnitus.[2] IEI-EMF has been found to be associated with
15 limitations in social and occupational functioning.[3 4] The prevalence of IEI-EMF is
16 estimated to be 1.5-5% of the population,[3 5 6] but also a prevalence as high as 13% has
17 been reported.[7] These differences are due to the population under study (Western countries
18 vs. Taiwan), and probably also the instruments or definitions that were used.[8] For the
19 Netherlands, an estimate of the prevalence of IEI-EMF is not yet available.
20
21 Scientific studies have not provided convincing evidence for the existence of a causal bio
22 electromagnetic mechanism for non-specific health symptoms.[9] Alternative explanations for
23 IEI highlight the role of psychological mechanisms such as hyper vigilance to threat stimuli,
24 attention bias and somatosensory amplification.[10] For IEI-EMF, some findings suggest that
25 *nocebo* responses account for the symptoms,[9 11] in which concerns about a perceived harm
26 precede the development of symptoms. Indeed, persons who suffer from IEI-EMF have
27 relatively high levels of mental distress, anxiety, depression, and worries about modern

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3 1 life.[12-14] Several studies have demonstrated a relationship between negative affect and
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5 2 non-specific health complaints.[15]
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9 4 Most evidence for the lack of an association between EMF exposure and non-specific
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11 5 physical symptoms is derived from short-term provocation studies in the laboratory, which
12
13 6 have been criticized because of their lack of internal and external (ecological) validity.
14
15 7 Criticisms include that a visit to the laboratory may cause anxiety that influences the results,
16
17 8 that EMF exposure in the experimental setting does not resemble real-life EMF exposure, and
18
19 9 that follow-up times are insufficiently long to capture participants' responses [9].
20
21 10 Observational studies are subject to other forms of bias due to errors in the recall of symptoms
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23 11 (recall bias) and in the assessment of EMF exposure.[16]
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27 13 The limitations mentioned above can be solved by ecological momentary assessment (EMA).
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29 14 With EMA, the assessment is momentary, on the spot in real life, and captures life as it is
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31 15 lived.[17 18] More precise and ecologically valid EMA-measurement of personal RF EMF
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33 16 exposure can be performed with exposimeters[19] This produces more valid estimates than
34
35 17 other methods such as self-reported exposure, geo-coded distance from sources of RF EMF
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37 18 (e.g. base stations) or spot measurements.[20] Recall bias of symptoms can be minimised by
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39 19 using EMA diary methods with short time frames instead of asking participants to
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41 20 retrospectively report (the usual frequency of) symptoms over a prolonged period.[21]
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45 22 This article describes the design of an EMA study on the relationship between real-life
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47 23 measured and perceived exposure to RF EMF and the real-time experience of non-specific
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49 24 physical symptoms and mood in self-declared electro hypersensitive people. The study
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51 25 intends to minimise sources of bias by using exposimeters to estimate RF EMF exposure and
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53 26 real time on the spot assessment of symptoms.
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1 Objectives

2 The key objective of the study is to determine if in a period of a few days non-specific
3 physical symptoms in persons who report to be sensitive to RF EMF can be explained by
4 objectively measured exposure to RF EMF, or by psychological measures such as perceived
5 exposure and mood. Secondary objectives are to study the manifestation of non-specific
6 symptoms in terms of severity and duration of symptoms, the lag time – in hours to days –
7 between exposure and the presentation of symptoms, and to characterise RF EMF exposure of
8 persons with IEI-EMF.

10 METHODS AND ANALYSIS

11 Study design

12 Epidemiologic panel studies, which have similarities to EMA studies, have been described as
13 ‘prospective studies that follow a usually small group of individuals intensively over a short
14 time period [...] with the objective to study short-term effects of a time-varying
15 environmental exposure’.[22] A main advantage of a panel design is the availability of
16 measurements of exposure and health outcomes at an individual level. The present study is an
17 EMA study in which, for five consecutive days, participants carry a measurement set
18 consisting of an RF EMF personal exposure meter, a so called exposimeter, a GPS (global
19 positioning system) logger and an electronic diary. The electronic diary assesses health
20 complaints, perceived exposure and mood. It has to be completed directly at frequent, random
21 alarm cues, as this prevents both recall bias and possibly planned high exposures shortly
22 before the time when filling out the diary. This design allows for studying whether non-
23 specific physical symptoms are preceded by exposure to EMF, using various latency times,
24 and/or whether these symptoms are related to psychological variables such as perceived
25 exposure and mood.

1 Selection of study population

2 Participants will be recruited from an existing epidemiological study (EMPHASIS) on non-
3 specific physical symptoms and their relation with model-estimated actual and perceived
4 EMF exposure.[23] This study includes 6304 persons that were selected from 21 general
5 practices throughout the Netherlands, varying in level of urbanisation and stratified according
6 to the distance of their residencies to a mobile telephone base station. The response rate to the
7 written questionnaire was approximately 50%.[24]

8 Participants will be selected from the respondents to this survey based on self-reported
9 sensitivity to EMF measured with a five-point scale. People who indicated to fully or partly
10 agree with the statement 'I am sensitive to antennas and devices using wireless
11 communication (e.g., for radio, television, mobile phones, wireless internet etc.)' and who
12 gave their consent to use their address for re-approaching, will be invited by post to
13 participate in the study. All study materials (diaries, exposimeters, and instructions) will be
14 delivered at the participants' homes, where they will be orally instructed about the study
15 procedures.

16 Electronic diaries

17 Diary methods are considered suitable to examine self-reported events and experiences in
18 their natural, spontaneous context. Benefits of diary methods are that bias in the recall of
19 events and experiences is reduced because the time between the occurrence of an event or
20 experience and its reporting is minimised.[17] Diary methods can properly address the
21 research question what the correlates and antecedents are of within-person variability in daily
22 experiences.[17]

23
24 The present study will use electronic diaries. Advantages of electronic diaries include a higher
25 participant compliance than paper and pencil diaries,[25] control of alarm cues, and a detailed
26 log file for compliance check.

27

1 For diary keeping we will use *LG P-500 Optimus One* smartphones running on Android 2.3.
2 Because the study population will consist of persons with IEI-EMF, the phone operates in
3 flight mode without a SIM card. A check of exposure to extremely low frequencies (Emdex
4 Lite, Enertech Consultants, California) and RF (EME Spy 121, Satimo, France) confirmed
5 that the exposure from the smartphone was negligible, i.e. below the detection limits.

6
7 Special software for the diaries was developed using Java (Android version 2.2 or higher).
8 The diary programme is based on software written for Palm-OS personal digital assistants
9 which has been developed and used by Houtveen et al..[26] A sampling protocol with a mean
10 interval of 2.5 hours and random variation of ± 30 minutes will be used that continues from
11 awakening till bedtime. This sampling scheme leads to approximately 8 alarms per day (based
12 on a 16-h awakening period). Diary prompting will only be disabled during sleep, initiated by
13 a button on the smartphone. The smartphone can be used as a morning alarm, and prompting
14 continues after awakening. All unused buttons are blocked. Alarms without response are
15 repeated (max 3 times with 10-min time intervals). The alarm software generates a log-file
16 containing alarm and response times to be used for determination of the compliance. The
17 questionnaire can be launched by a start button that is visible for 5 min after prompting. All
18 questions are forced-choice, and are displayed as sequential screens on the smartphone.
19 Participants will not be allowed to leaf through the present or previous diaries. The volume of
20 the alarms is adjustable and there is the possibility to temporarily mute the alarm.

21 22 **Diary questionnaire**

23 The diary questionnaire consists of 32 items. In the morning and evening, 5 and 8 additional
24 questions are included, respectively. According to guidelines for diary questions, the items are
25 short, simply worded, and try to mimic the participants' internal dialogue, e.g. 'at the
26 moment, I suffer from headache'.

27

1 General health status and non-specific physical symptoms
2
3 General health status will be assessed by using the first question from the RAND-36.[27]
4
5 Nine symptoms are selected that are most often reported by electro hypersensitive people
6
7 according to studies in Switzerland[2] and a survey among members of the Dutch
8
9 Electrohypersensitivity Foundation.[28] These symptoms comprise of fatigue,
10
11 distressed/nervous/tense feeling, concentration problems, tinnitus, dizziness or light-
12
13 headedness, painful joints or muscles, skin problems, problems with vision, hearing or smell.
14
15 In addition, one question asks for the symptom that the participant usually experiences and
16
17 that is not in the pre-specified list. For all symptoms the momentary experience is assessed
18
19 ('at this moment, ...'). Response options range from 'not at all' to 'very much' on a five-point
20
21 Likert response format with only the extremes labelled.
22
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27 Perceived exposure to (sources of) RF EMF, noise and air pollution
28
29 Perceived exposure to RF EMF will be assessed both momentary and for the interval between
30
31 alarm cues, using the question 'At the moment/since the last alarm cue, I am exposed to radio
32
33 frequent electromagnetic fields', with response options ranging from 'not at all' to 'very
34
35 much' on a five-point scale with only the extremes labelled. Perceived exposure to specific
36
37 sources of RF EMF is assessed by asking the participant to indicate which of the following
38
39 sources mainly determined their exposure: mobile phone, DECT phone, WiFi, antennas for
40
41 mobile telephony, radio or television masts, another source.
42
43

44 Momentary (but not for the interval between alarm cues) exposures to noise and air pollution
45
46 are asked in a similar way.
47
48

49 Environment
50

51 In order to interpret the readings of the exposimeter, participants will be asked to indicate in
52
53 what kind of environment they were during the interval between alarm cues. The
54
55 environments included are at home inside, at home outside, elsewhere inside, elsewhere
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1
2
3 1 outside, on the road (on foot, by bike, car or public transport), in the city centre or a shopping
4
5 2 area, in a residential or built-up area but not the centre, outside the built-up area (e.g., in a
6
7 3 rural area or in nature). All participants already completed a detailed time-activity
8
9 4 questionnaire on their general behaviour in the EMPHASIS study.[23]
10

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14 6 Self-reported use of mobile phone and DECT phone

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16 7 Phone use will be estimated separately for mobile phones and DECT phones by asking how
17
18 8 many minutes a person called in the interval between alarm cues: 1-5, 5-10, 10-10, 20-30, 30-
19
20 9 60 or longer than 60 minutes. In addition, participants will be asked to register on a form their
21
22 10 use of mobile and DECT phones.
23

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26 12 Mood

27
28 13 The Profile of Mood States (POMS)[29] will be used to assess momentary (state) depression,
29
30 14 vitality, anger, and tension. Three items for each subscale will be used, as was done
31
32 15 previously by Houtveen and Van Doornen.[30] The selected items were: (1) depression:
33
34 16 unhappy, sad, hopeless, (2) vitality: active, energetic, lively, (3) anger: angry, annoyed,
35
36 17 moody, (4) tension: tense, nervous, anxious. Each item can be rated using a five-point Likert
37
38 18 response format ranging from 'not at all' to 'very much' with only the extremes labelled.
39

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42 20 Additional questions

43
44 21 After the morning alarm cue, the diary contains some questions about the duration and quality
45
46 22 of sleep. Before the participants go to bed, questions are asked about use of medication to
47
48 23 relieve their symptoms (mentioned in the diary), avoidance of sources of RF-EMF because of
49
50 24 their symptoms, and whether the participants rested or took a nap during daytime.
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54 25 **Personal RF exposure assessment**

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56 26 Actual EMF exposure will be measured using EME-SPY 121 exposimeters (Satimo,
57
58 27 Cortaboeuf, France) worn at the hip in a camera bag. As the maximum memory capacity of
59
60

1 the exposimeter is 12,540 sampling intervals and the study will last for 120 hours, the
2 exposimeter will measure at an interval of 36 seconds. The exposimeters measure the RF
3 electric field strength in 12 frequency bands used for communication and broadcasting (see
4 Appendix 1). Before the exposimeters will be employed in the study, they will be calibrated
5 according to a previously described method,[19] modified in a way that the calibrations take
6 place in an anechoic chamber instead of a Gigahertz Transverse Electromagnetic cell
7 (GTEM).
8 The participants will be instructed to wear the exposimeters all day except during wet
9 activities (e.g. showering) and sports (to avoid damage due to shocks). During sleep, the
10 exposimeters have to be placed next to the bed within 50 cm from the head. The electronic
11 diary contains an event button that can be used to indicate when the exposimeters are worn or
12 taken off.

13 **GPS logger**

14 Participants will wear a GPS device at their left shoulder. The GPS logger geo-locates the
15 personal RF EMF measurements and the data can be used to visualize the participants'
16 location and measured EMF exposure on a Google Earth map.[31 32] This visualization can
17 be used to interpret and check the quality of the EMF measurements.

18 **Data analysis**

19 Exposimeter data will be aggregated either over fixed time intervals or over intervals between
20 random alarm cues, and for each interval the time weighted average, peak exposure, exposure
21 above a certain threshold and rate of change can be calculated for all frequency bands
22 separately and combined. The relationship of actual and perceived EMF exposure with non-
23 specific physical symptoms will be analysed using multilevel regression analysis. The within-
24 subject repeated measurements of actual and perceived EMF exposure and mood will be the
25 first-level variables, which will be modelled as fixed effects; the second level will be the
26 individuals and will be modelled as random effects. Because time (hour of the day) is

1 associated with symptom occurrence and severity (e.g. for fatigue), this will be included in
2 the model using a sinus-cosinus 24 hour function to account for the diurnal pattern. Unique
3 contributions of the various explanatory variables will be estimated in multivariate models, in
4 which an intercept, 24 hour time function, actual EMF exposure, perceived EMF exposure
5 and mood will be included. Time-shift models with different lag times will be used to gain
6 insight in the time delay between exposure and mood and the occurrence of symptoms. The
7 time window of five days should be sufficient to capture the potential participants' response
8 to EMF exposure, based on reported latencies between exposure and symptoms.[2]

9 A multilevel power analysis was performed to calculate the strength of the association
10 between perceived EMF exposure and nonspecific physical symptoms that could be detected
11 with the repeated measurements multilevel analysis in a sample of 60 volunteers with each 40
12 (5 days with 8 measurements) observations. A significance level of 5% and a power of 80%
13 was used. This method based on simulations is described previously.[33] No such calculation
14 was made for actual EMF exposure because most evidence points towards the absence of an
15 association with nonspecific physical symptoms.

16 Input parameters for the power analysis came from a pilot study of four (not electro
17 hypersensitive) master students (two males, two females) who completed the diary questions
18 for two weeks.[unpublished data, National Institute for Public Health and the Environment
19 2012] Figure 1 illustrates how the power of the statistical analysis differs according to the
20 magnitude of the regression coefficient. It can be seen that at a power of 80%, the detectable
21 regression coefficient is slightly over 1.5, which corresponds to an increase of 1.5 on the sum
22 of 10 symptoms (range 0-40) at an increase of 1 in perceived exposure (range 0-4)

23 **ETHICS AND DISSEMINATION**

24 A formal written inquiry, including a detailed description of the study protocol, was made at
25 the medical ethics committee of the University Medical Centre Utrecht to check if the study
26 protocol should be tested within the framework of the Dutch Medical Research Involving
27 Human Subjects Act. A formal advice was received in which the Committee indicated that the

1 study was exempt from having to pass the full ethics testing procedure. Handling of personal
2 data will comply with the Personal Data Protection Act [in Dutch: Wet bescherming
3 persoonsgegevens (Wbp)]. After removal of identifying information, data will be stored on a
4 part of the institute's server with limited access by specified employees.

5 Results of the study will be offered for publication in the international peer-reviewed
6 literature and presented at (international) conferences. Further, results will be disseminated at
7 a national level at meetings organized by The Netherlands Organisation for Health Research
8 and Development (ZonMw). At these meetings representatives of IEI-EMF patient groups
9 will also be reached.

11 **DISCUSSION**

12 The EMA design of this study is innovative as it combines actual exposure measurements
13 with momentary measured health symptoms. The design aims to circumvent important
14 limitations of previous studies into IEI-EMF, which can be summarised as biased recall of
15 health outcomes, poor characterisation of individual exposure to EMF, and experimental
16 exposure conditions that substantially differ from the real-life situation (i.e. low ecological
17 validity). Another potential strength of the study is the simultaneous assessment of actual and
18 perceived EMF exposure. In the multilevel regression analysis, independent contributions of
19 these two types of exposure can be estimated, an approach similar to the EMPHASIS
20 study.[23] With respect to recall bias, it has been shown that especially in people with high
21 levels of non-specific physical symptoms, less symptoms are reported when using momentary
22 assessment methods compared to retrospective methods.[34] Since persons with IEI-EMF
23 typically report more symptoms than the general population,[35] a symptom diary is more
24 suitable to obtain a valid estimate than asking to report the usual or average number of
25 symptoms retrospectively.

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3 1 Regarding the EMA-measurement of exposure, exposimeters are the method of choice to
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5 2 measure personal exposure compared to spot measurements, self-estimated exposure, and
6
7 3 exposure prediction models.[20] Nevertheless, also measurements of exposimeters have their
8
9 4 own limitations and are not always free of bias. To obtain valid measurements, it is important
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11 5 that the participants receive clear and standardised instructions about how to wear the meters.
12
13 6 In this way measurements by different participants will be harmonised and more
14
15 7 comparable.[19] Exposure from mobile phone use by the participants themselves will not be
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17 8 measured properly by the exposimeter, because the exposimeters are designed to measure the
18
19 9 far EMF field, i.e. exposure from EMF sources further away. In the near field, the
20
21 10 exposimeters are unable to correctly measure the exposure, resulting in overestimations or
22
23 11 'clipping' in which the maximum measurement value of 10 V/m is registered. Therefore,
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25 12 mobile phone use during each 2.5 hour interval between alarm cues is asked for in the diaries
26
27 13 (although we are aware of the recall bias in the estimates of self-reported phone use) and
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29 14 participants are requested to register their use of mobile and DECT phones.
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33 16 Another strength of using individual-level exposure and outcome data is that confounding by
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35 17 factors that remain stable over time is reduced, because within-subject variation in exposure
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37 18 and manifestation of health symptoms are of primary interest. Thus, the analyses do not
38
39 19 require adjustment for personal characteristics such as demographic factors and psychological
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41 20 traits. However, to detect possible interaction effects, e.g. different associations in men and
42
43 21 women, personal characteristics have to be taken into account. The multilevel regression
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45 22 analysis allows for such an investigation of cross-level interactions. Because the study
46
47 23 population may be a mix of 'truly' electrosensitive individuals and individuals in whom
48
49 24 psychological mechanisms account for their symptoms, we will explore the applicability of
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51 25 statistical methods to study associations that differ between individuals (vector autoregressive
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53 26 models[36]).
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55 27 Time-varying factors associated with EMF exposure [32] that potentially affect symptom
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57 28 occurrence also need to be accounted for. Avoidance of EMF exposure after symptoms start
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1 to develop is such a factor (which is asked for in the diary). Time-varying factors associated
2 with symptoms but not with EMF exposure are no confounders, but can obscure relationships
3 between exposure and symptoms. This is the reason a question about the use of medication to
4 relieve symptoms and rest/sleep during the day is included in the diary questionnaire.

5
6 There are also limitations to the described study. Although the external (ecological) validity
7 of the design is high, compared to double-blind trials such as provocation studies in the
8 laboratory, the internal validity is lower. Further, the study involves relatively high costs in
9 terms of the necessary equipment and work. The exposimeters are expensive and vulnerable
10 to physical damage, and the electronic diaries are also costly compared to traditional paper
11 and pencil diaries. Also, the programming of the diary software is very time consuming. As a
12 result, only a limited number of participants can be included in the study. The burden for
13 participants is quite high, since they have to carry the exposimeters and GPS loggers with
14 them and are interrupted by the diary alarm cues several times a day. It is expected that only
15 highly motivated persons will participate, but because the study is not intended to examine a
16 representative sample of the population this is not considered a problem. Compliance to the
17 study protocol may be difficult for some participants because they may find wearing the
18 exposimeter awkward. As a result of participation in the study, the participants' attention to
19 EMF exposure and physical symptoms may increase (reactivity). It can in principle not be
20 excluded that the data are manipulated by placing the meters next to a (assumed) source of
21 EMF before an alarm cue is expected. To minimise the chance of such anticipation effects,
22 the alarms are programmed at random intervals. Further, unusual exposure patterns can be
23 checked for, although high and prolonged exposure peaks can be real and do not have to
24 result from anticipation effects.

25
26 In the statistical analysis, false-positive associations due to multiple testing may arise. For
27 EMF exposure, there is information about 12 frequency bands, which can be analysed
28 separately and combined. Possible exposure metrics include time-weighted average, peak

1 exposure, rate of change and exposure above a certain threshold. Since no biological
2 mechanism is known that explains how EMF can affect health, in theory each combination of
3 almost 50 combinations of frequency and exposure metrics can be relevant. To take into
4 account the possibility of false-positive associations, the expected proportion of falsely
5 rejected hypotheses will be controlled using a sequential Bonferroni-type procedure described
6 by Benjamini and Hochberg.[37] If associations with symptoms are found, it is necessary to
7 replicate the results to exclude chance findings. Also, it should be noted that significant
8 relationships between RF-EMF exposure and symptoms not necessarily have to be causal
9 relationships.

10
11 An issue that deserves attention is the selection of the study population. Since no objective
12 diagnostic tool for IEI-EMF exists, the only selection criterion for inclusion in the study is
13 self-reported sensitivity to RF EMF. No further selection will be made based on the
14 occurrence of non-specific physical symptoms as this is the outcome variable of the study.
15 Also, no exclusions will be made based on psychological variables. The reason for this is that
16 IEI-EMF often goes together with psychological problems such as depression and
17 anxiety,[12] and especially in the most sensitives psychiatric morbidity has been reported to
18 be high.[7] Therefore, by excluding persons based on psychological characteristics the study
19 population of interest may be missed. Somatic (chronic) diseases will not be excluded either,
20 as a considerable part of persons having IEI-EMF suffer from chronic diseases,[35] and at this
21 stage it is not possible to decide on theoretical grounds which medical conditions should be
22 included or excluded.

23
24 A control group is not deemed necessary, since in the longitudinal study design each
25 participant acts as their own control. Moreover, if there are associations between RF EMF
26 exposure and symptoms, this will be most likely in persons who report to be sensitive to RF
27 EMF, and statistical power will be enhanced by focusing on this group. A limiting factor of

1 this approach is that we cannot verify if persons with IEI-EMF are more sensitive to EMF
2 than controls.

3
4 In summary, this is the first time that actual and perceived exposure and possibly explanatory
5 variables are combined to such extent in an IEI-EMF sample. The main strengths of the study
6 described in this paper are an accurate assessment of EMF exposure and non-specific physical
7 symptoms using an EMA methodology, and elimination of confounding by personal
8 characteristics as a result of the within-person design. The methodological issues mentioned
9 above will be accounted for and limited as much as possible in the conduct of the study as
10 well as the analysis and interpretation of its outcomes.

11

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4 **1 LIST OF ABBREVIATIONS USED**

5
6 2 DECT: Digital enhanced cordless telecommunications

7
8 3 EMA: ecological momentary assessment

9
10 4 EMF: electromagnetic fields

11
12 5 RF: radiofrequency

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15 **6 COMPETING INTERESTS**

16
17 7 The authors declare that they have no competing interests.

18
19
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21
22 9 This work is financially supported by The Netherlands Organisation for Health Research and
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11 **AUTHORS' CONTRIBUTIONS**

12 RPB conceived of the study, participated in its design and coordination, and drafted the
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13 critically for important intellectual content. JHH participated in the study design and helped to
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14 revise the manuscript critically for important intellectual content. EL conceived of the study,
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22 critically for important intellectual content. IvK participated in the study design, permitted
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23 access to the EMPHASIS dataset and helped to revise the manuscript critically for important
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24 intellectual content. All authors read and approved the final manuscript.

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For peer review only

1 **FIGURE LEGEND**

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3 Figure 1. Power of the repeated measurements multilevel regression analysis as a function of
4 the magnitude of the regression coefficient, n=60 persons with 40 repeated measurements.
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APPENDIX 1

The 12 frequency bands measured by the exposimeter are: FM radio (88–108 MHz), TV3 (174–223 MHz), TETRA (380–400 MHz), TV4&5 (470–830 MHz), GSM uplink (880–915 MHz), GSM downlink (925–960 MHz), DCS uplink (1710–1785 MHz), DCS downlink (1805–1880 MHz), DECT (1880–1900 MHz), UMTS uplink (1920–1980 MHz), UMTS downlink (2110–2170 MHz), and WiFi (2400–2500 MHz). The formerly TV3 and TV4&5 frequency bands are nowadays used for digital radio, Terrestrial Digital Audio Broadcasting (T-DAB), and digital TV, Digital Video Broadcasting Terrestrial (DVB-T), respectively. Uplink means that the signal is used for the contact from mobile phone to base station, downlink is from base station to mobile phone.

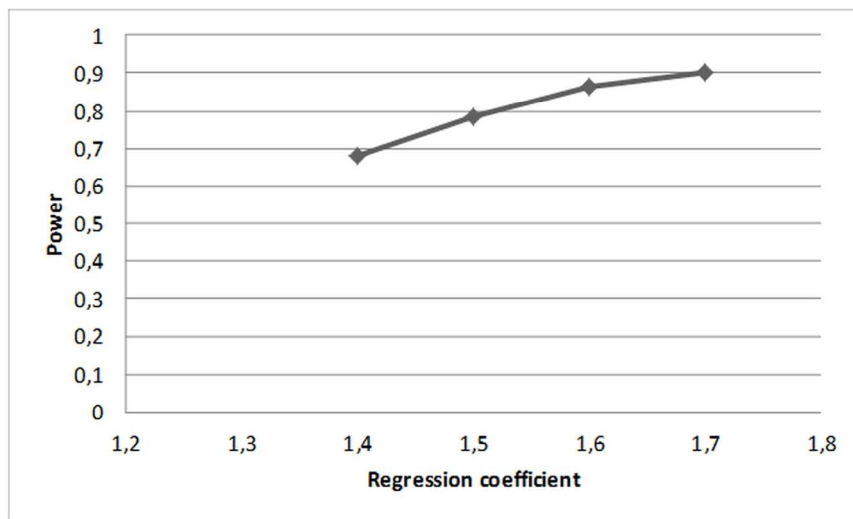


Figure 1. Power of the repeated measurements multilevel regression analysis as a function of the magnitude of the regression coefficient, n=60 persons with 40 repeated measurements.

144x90mm (300 x 300 DPI)

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